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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,840	06/20/2000	Dewen Qiu	19603/3340 (CRF D-2018B)	6516

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Michael L Goldman
Nixon Peabody LLP
Clinton Square
PO Box 31051
Rochester, NY 14603

EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/597,840	QIU ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-44 and 46-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *52-59* is/are allowed.

6)☒ Claim(s) *38-44 and 46-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 38-44 and 46-59 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 39-44 and 51 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's amendment of the claims.

Claim Rejections - 35 USC § 112

4. Claims 38-44 and 46-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 9 April 2004. Applicant's arguments filed 13 October 2004 have been fully considered but they are not persuasive.

Applicant urges that the Federal Circuit has stated that conclusions of written description violations cannot be founded on the basis of genus size alone, citing *Enzo* (response pg 5-6).

This is not found persuasive because in *Enzo*, the issue was remanded; no decision made as to whether a description of three sequences was sufficient to describe the genus (*Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609 (CAFC 2002), pg 1615). Furthermore, the circumstances of that case differ from the instant case, as the claims in *Enzo* were drawn to

variants of the deposited sequences, while the instant claims are drawn to use of any nucleic acid that encodes a hypersensitive response elicitor protein from any bacterial plant pathogen.

Applicant urges that the specification teaches that those of skill in the art could use nucleic acids that encode hypersensitive response elicitor proteins identified after the filing date, and that the written description guidelines make it clear that a description of a representative number of species does not require the description to be of such a nature that it would provide support for each species of the genus; thus, the absence of sequences for the HrpW elicitors is irrelevant (response pg 6).

This is not found persuasive. The citation the HrpW, dspE and dspF genes was to indicate that the instant specification fails to describe a representative number of nucleic acids that encode hypersensitive response elicitor proteins from even a single species, much less three genera or any bacteria.

Applicant urges that as demonstrated in the Declarations of Dr. Wei submitted 25 September 2002 and 21 January 2003 one of ordinary skill in the art would have understood that Applicant was in possession of the invention because the 4 exemplary species were recognized at the time of filing as belonging to an art-recognized class of hypersensitive response elicitor proteins (response pg 6).

This is not found persuasive because the 4 exemplary species do not describe the full scope of the claims. There are at least 12 *Erwinia* species; the instant specification only describes two nucleic acids encoding hypersensitive response elicitors from two species. There are at least 113 *Pseudomonas* species; the instant specification only describes two nucleic acids encoding hypersensitive response elicitors from two species. These four sequences are not a

representative number of hypersensitive response elicitors from *Erwinia* and *Pseudomonas*, much less from all bacterial pathogens. Furthermore, the specification fails to describe the structural features that distinguish hypersensitive response elicitors from bacterial plant pathogens from hypersensitive response elicitors that are not plant pathogens.

Additionally, the instant specification only describes two non-full-length fragments of hypersensitive response elicitors from one *Xanthomonas* species and describes no nucleic acids encoding full-length hypersensitive response elicitors from any *Xanthomonas* species.

See *In re Wallach*, 71 USPQ2d 1939 (CA FC 2004), at pg 1939:

> Claims in application directed to isolated DNA molecules encoding proteins that inhibit cytotoxic effects of tumor necrosis factor were properly rejected for failure to satisfy written description requirement of 35 U.S.C. §112, since applicants claimed nucleic acids encoding protein for which they provided only partial sequence, and without approximately 95 percent of amino acid sequence that applicants did not disclose, it cannot be held that DNA molecules claimed in application have been described, since applicants' contention that they were in physical possession of protein does not establish their knowledge of that protein's amino acid sequence or any of its other descriptive properties, even though amino acid sequence is inherent property of protein, and since application does not provide adequate functional description , in that, with only partial amino acid sequence disclosed, chemical structure of nucleic acid molecules that can serve function of encoding protein's amino acid sequence cannot be determined.

Applicant urges that hypersensitive response elicitor proteins are often homologous to elicitors from different species and strains, and can be used to clone other hypersensitive response elicitor genes, citing the Declaration of 21 January 2003. Applicant also urges that Jock et al teaches that PCR amplification was used to clone other hypersensitive response elicitor genes (response pg 6-7).

This is not found persuasive. "Often homologous" indicates that the structure of hypersensitive response elicitors from bacterial plant pathogens has not been described within the full scope of the claims. Furthermore, Jock et al teach that "[g]enes encoding harpins are highly divergent even for related bacteria" (paragraph spanning the columns on pg 488). Lastly, that that PCR amplification based on one hypersensitive response elicitor sequence can be used

to clone some hypersensitive response elicitor genes does not mean that a representative number of all hypersensitive response elicitor genes are described.

Applicant urges that the disclosed species are representative of the claimed genus because the encoding genes are similarly regulated, expressed and secreted and located in similar positions in their operons, citing the Declaration of 21 January 2003 (response pg 7).

This is not found persuasive. Regulation and expression are determine by regulatory sequences, not by the coding sequences for the hypersensitive response elicitor, and secretion is determined by only a small portion of the protein coding sequence, and thus does not describe the entire sequence.

Applicant urges that the disclosed species are representative of the claimed genus because they are characterized by common biochemical characteristics, including being glycine rich, heat stable, hydrophilic, lacking N terminal signal sequence and susceptible to proteolysis, citing the Declaration of 21 January 2003 (response pg 7).

This is not found persuasive. Bogdanove et al (2001, US Patent 6,228,644) teaches that the hypersensitive response elicitor dspE and dspF are homologous with genes in the avrE locus of *Pseudomonas syringae* pv. *tomato*, not to harpins (column 34, line 64, to column 35, line 43). Thus, hypersensitive response elicitors from bacterial plant pathogens do not share the biochemical characteristics of being glycine rich, heat stable, hydrophilic, lacking N terminal signal sequence and susceptible to proteolysis

Applicant urges that the disclosed species are representative of the claimed genus because they share the ability to induce plant responses, citing the Declaration of 21 January 2003 (response pg 8).

This is not found persuasive. Inducing plant responses only describes a function of the elicitors; it does not describe the structure.

Applicant urges that with respect to growth enhancement, both topical application and transgenic expression have proven helpful, citing the Declaration of 21 January 2003; thus, one of skill in the art would expect other members to likewise induce growth (response pg 8).

This is not found persuasive. The rejection is not an enablement rejection for the ability of hypersensitive response elicitors to induce growth. The rejection is a written description rejection, because hypersensitive response elicitors are not described within the full scope of the claims.

Applicant urges that they have present a body of evidence demonstrating that the 4 species belong to an art-recognized class of proteins with structural conservation, similar expression and secretion, and common biochemical characteristics, while the PTO did not demonstrate that the genus contains structurally and functional unrelated species (response pg 8).

This is not found persuasive. See the teachings of Bogdanove et al, discussed above. Additionally, as noted above, Jock et al teach that "[g]enes encoding harpins are highly divergent even for related bacteria" (paragraph spanning the columns on pg 488).

5. Claims 38-44 and 46-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of enhancing growth in plants by growing a plant or seed that has been transformed with a nucleic acid that encodes SEQ ID NOs:2, 4, 6 or 8, does not reasonably provide enablement for a method of enhancing growth in plants by growing a plant or seed that has been transformed with a nucleic acid encoding other

hypersensitive response elicitors from *E. chrysanthemi*, *E. amylovora*, *P. solanacearum* or *P. syringaes* or nucleic acids encoding hypersensitive response elicitors from *Xanthomonas campestris* or from any other *Erwinia*, *Xanthomonas* or *Pseudomonas* species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 9 April 2004. Applicant's arguments filed 13 October 2004 have been fully considered but they are not persuasive.

Applicant urges that one of ordinary skill in the art is capable of identifying other nucleic acids encoding hypersensitive response elicitors and transforming plants, citing the Wei Declaration of 21 January 2003 (response pg 9).

This is not found persuasive. The specification must provide guidance for nucleic acids encoding hypersensitive response elicitors within the full scope of the claims, and the instant specification fails to do so. The specification does not teach any nucleic acid encoding other hypersensitive response elicitors from *E. chrysanthemi*, *E. amylovora*, *P. solanacearum* or *P. syringaes* or nucleic acids encoding hypersensitive response elicitors from *Xanthomonas campestris* or from any other *Erwinia*, *Xanthomonas* or *Pseudomonas* species. The rejection is not for methods of plant transformation.

6. Claims 52-59 are allowed.

Conclusion

7. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Anne R. Kubelik, Ph.D.
January 7, 2005